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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/420,719	10/20/1999	MARIKO MIYASHITA	10059-308(P2	3194

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EXAMINER	
PADMANABHAN, KARTIC	

ART UNIT	PAPER NUMBER
1641	

DATE MAILED: 02/05/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/420,719	MIYASHITA ET AL.	
	Examiner	Art Unit	
	Kartic Padmanabhan	1641	

-- The MAILING DATE of this communication appears on the cover sheet with the corresp ndence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *31 October 2003*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *19,24,25,29 and 30* is/are pending in the application.

4a) Of the above claim(s) *30* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *19,24,25 and 29* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *19,24,25,29 and 30* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *20 October 1999* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

13)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

a) ☐ The translation of the foreign language provisional application has been received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Election/Restrictions

1. Applicant's traversal of the restriction of claim 30 from the originally presented invention in Paper No. 25 is acknowledged. The traversal is on the ground(s) that the search of both groups is not an undue burden, and the limitations of claim 30 have been previously presented. This is not found persuasive for reasons of record set forth in the previous office action. It is also noted that in so far as the limitations of claim 30 have been previously presented, the claims contained the limitations of claim 30 in the alternative or as part of a Markush group, and never required all the elements of currently recited claim 30. Specifically, the previously presented claims never required an absorbent in addition to another element selected from the group consisting of a catalyst and a buffer, as claim 30 now does; rather, the previously presented claims only required ***one*** of an absorbent, catalyst, and buffer as the control means.

The requirement is still deemed proper and is therefore made FINAL.

2. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

3. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

5. The factual inquiries set forth in *Graham* v. *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

6. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

7. Claims 19, 24, and 25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Obata et al. (US Pat. 5,571,419) in view of Short et al. (US Pat. 6,183,740 B1) or Lihme et al. (US Pat. 5,935,442).

Obata et al. teach a method and apparatus for producing pure water. According to the reference, raw water is introduced into filtration units through a pipe and treated. After undergoing cation exchange, the water is supplied to an acidic softened water tank and stored. It is inherent that the pH of the raw water is altered in some way in this tank. An oxidizing agent, which may be hydrogen peroxide, is added to the raw water through a pipe. A heater provided with a boiler then heats the water. The water is then introduced into a reaction chamber where urea is decomposed by catalytic heat treatment. At the end of the process, the now pure water is released (col. 4, lines 30-67 and Figs. 1-8). Since well water and tap water can be filtered using the apparatus of the reference, it is inherent that the purified water is fit for human consumption in some fashion, and a person tasting water is interpreted as a biosensor analyzing a sample. However, the reference does not teach the use of enzymes as the catalyst.

Short et al. teach the use of phytases in water treatment. The reference teaches that biological enzymes are effective in the bioconversion of potentially noxious substances into useful bioproducts.

Lihme et al. teach water treatment, wherein the active substance may be an enzyme, catalyst, or other treatment material.

It would have been *prima facie* obvious to one of ordinary skill in the art at the time of the invention to use enzymes for water treatment as in Short et al. or Lihme et al. with the treatment method of Obata et al. because both Short et al. and Lihme et al. teach that enzymes are useful in water treatment methods. In addition, Lihme et al. contemplate the use of various agents for water treatment, including catalysts and enzymes, which would give one of skill in the art a reasonable expectation of success in using any number of agents, such as enzymes, to

convert noxious substances into harmless ones, depending on the makeup of the water being treated.

8. Claims 19 and 25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Yasuda et al. (US Pat. 5,378,635). Yasuda et al. teach a method of measuring catecholamine. The reference discloses sample pretreatment means and sample dispensing means in the form of a syringe, which is couple to the pretreatment means. A syringe inherently has sample introduction and sample releasing parts. Maleimide, mixed with a buffer solution to adjust the pH to around 7.3, is added to the sample dispensing means or the sample pretreatment means and reacts with SH compounds, which inhibits the interference of fluorescence inducing reaction. However, the reference does not teach that the sample pretreatment means is physically independent of the biosensor.

It would have been *prima facie* obvious to one of ordinary skill in the art at the time of the invention to make the pretreatment means separable from the biosensing means, since it has been held that constructing a formerly integral structure in various elements involves only routine skill in the art. *Nerwin v. Erlichman*, 168 USPQ 177, 179. In addition, in this case, it is noted that although the syringe may be connected to the biosensing means via tubing, the syringe can be made separable from the biosensor by simply removing it from the tubing. As such, after the sample is pretreated in the syringe, the syringe can then be attached to the tubing to convey the treated sample to the biosensor.

9. Claims 19 and 25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Heller et al. (US Pat. 5,262,305), Foulds et al. (US Pat. 5,124,253), or Nankai et al. (US Pat. 4,431,507).

Heller et al. teach a biosensor including an interferant eliminating catalyst. The apparatus of the invention has an interferant eliminating layer, including a catalyst, wherein the catalyst is capable of oxidizing and thereby eliminating a plurality of interfering compounds from the sample before it reaches the sensor (col. 1). The catalyst mediates oxidation of an interferant in the presence of an oxidant to yield a non-interfering compound that does not interfere with the biosensor's function. In addition, the catalyst may be a natural enzyme (col. 4). Furthermore, the apparatus of the reference inherently includes a sample introducing part and sample releasing part, as these parts are interpreted as any part of the apparatus that allows the entry and release of a sample. These parts are also located on either sides of the control means, as a sample enters the top of the layer, travels through the layer, where interferants are removed, and then is released to the sensing layer from the bottom of the interferant removing layer (figures 2 and 3).

Foulds et al. teach a device and method, wherein isozymes are employed to remove or inactivate endogenous alkaline phosphotase, thereby minimizing interference. In addition, the system also comprises a suitable buffer to alter the pH of the sample solution, often blood with a pH of 7.4, to an alkaline value suited to the enzyme of the test element (col. 4). The apparatus of the reference inherently includes a sample introducing part and sample releasing part, as these parts are interpreted as any part of the apparatus that allows the entry and release of a sample. These parts are located on either sides of the control means, as a sample enters one side of the layer, travels through the layer, where interferants are removed, and then is released on the other side.

Nankai et al. teach a device in which an electrode is provided to electrochemically oxidize interfering materials in the sample solution. The enzyme of the electrode oxidizes

interfering materials such as uric or ascorbic acid (col. 3). The apparatus of the reference inherently includes a sample introducing part and sample releasing part, as these parts are interpreted as any part of the apparatus that allows the entry and release of a sample. However, none of the references teach sample pretreatment means that is physically independent of the biosensor.

It would have been *prima facie* obvious to one of ordinary skill in the art at the time of the invention to make the pretreatment means separable from the biosensing means of the references, since it has been held that constructing a formerly integral structure in various elements involves only routine skill in the art. *Nerwin v. Erlichman*, 168 USPQ 177, 179.

10. Claim 29 is rejected under 35 U.S.C. 103(a) as being unpatentable over Obata et al. (US Pat. 5,571,419) in view of Short et al. (US Pat. 6,183,740 B1) or Lihme et al. (US Pat. 5,935,442) as applied to claims 19, 24, and 25 above, and further in view of Blatt et al. (US Pat. 5,945,345).

Obata et al., Short et al. and Lihme et al. teach a pretreatment device, as previously discussed. However, the references do not teach elastic sample supply means.

Blatt et al. teach a device for removing interferants comprising a filter including a solid phase support and an active chemical component for binding and immobilizing the interferant. In one embodiment, a sample is introduced to a solid phase support where the interfering substance is immobilized, and the "clean" sample is released. The device of the reference may also comprise a sample pad made of nylon, which is inherently elastic (stretchable). The sample is supplied to this pad, which qualifies this component as a sample supply unit. This unit has not been limited in any way to a unit that supplies a sample to the biosensor.

It would have been *prima facie* obvious to one of ordinary skill in the art at the time of the invention to use elastic sample supply means as in Blatt et al. with the modified device of Obata et al., Short et al. and Lihme et al. because an elastic supply unit allows for controlling sample release by compressing the elastic material in some way. In addition, one of skill in the art could have used a sample supply means made of any number of materials with the modified device of Obata et al., Short et al. and Lihme et al. with a reasonable expectation of success.

Response to Arguments

11. Applicant's arguments filed 10/31/03 have been fully considered but they are not persuasive.

12. Applicant argues that Obata does not disclose consumption of water by humans, which is interpreted as the biosensor, such that contamination with urea would not be an interferant. This is not convincing because the disclosure that the purified (free of urea as an interferant) water is used for well and city water renders human consumption inherent. In addition, both Short and Lihme at minimum generally disclose the use and effectiveness of enzymes in wastewater treatment. For example, Lihme teaches that an enzyme may be the active material used to purify water (Col. 12, lines 16-24). In addition, while the examiner acquiesces that Obata does not teach enzymes for interferant removal, the secondary references cure this deficiency, for reasons discussed under 35 USC 103; therefore, using the teachings of Short or Lihme regarding the use of enzymes in water treatment, one would have had the motivation to modify the teaching of Obata to use enzymes for water treatment with a reasonable expectation of success.

13. Applicant's argument that the references do not teach analysis by a biosensor that electrochemically measures a specific component is moot because such a limitation is merely the

intended use of the sample after treatment. A recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. In a claim drawn to a process of making, the intended use must result in a manipulative difference as compared to the prior art. See *In re Casey*, 152 USPQ 235 (CCPA 1967) and *In re Otto*, 136 USPQ 458, 459 (CCPA 1963).

14. Applicant argues that the Yasuda reference teaches that the sample already has buffer before it is inserted into the control means (syringe); however, while this may be the case, the buffer still exerts its effect while in the syringe, such that the limitation of a control means that may be buffer is met. In addition, applicant's arguments that it is inefficient to separate the syringe from the fluorometer are unconvincing. One of skill in the art at the time of the invention would have recognized that a syringe is easily removable from the biosensor of the reference, and would have numerous reasons for actually removing the syringe from the tubing attaching it to the biosensor, such as replacement or cleaning. Further, the courts have held that constructing a formerly integral structure in various elements involves only routine skill in the art. *Nerwin v. Erlichman*, 168 USPQ 177, 179.

15. Applicant also argues that there is no motivation in Heller, Foulds, or Nankai to separate the control means from the biosensor means; however, courts have held that constructing a formerly integral structure in various elements involves only routine skill in the art. *Nerwin v. Erlichman*, 168 USPQ 177, 179. There is no requirement that the combination be more efficient or better in any way.

16. Finally, applicant argues that the Blatt reference fails to teach an elastic material, which is also not convincing. The examine maintains that the nylon pad of Blatt is inherently elastic. While applicant is correct in asserting that the nylon pad must necessarily be elastic under the doctrine of inherency, the examiner maintains that it is. While various factors affect elasticity, as applicant points out, the nylon pad inherently possesses some degree of elasticity, and as applicant has not recited any requirement on the degree of elasticity, the claim limitation is deemed met.

Conclusion

Claims 19, 24, 25, and 29 are rejected.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kartic Padmanabhan whose telephone number is 703-305-0509. The examiner can normally be reached on M-F (8:30-5:00).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on 703-305-3399. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Kartic Padmanabhan
Patent Examiner
Art Unit 1641

*** KP

Christopher L. Chin

CHRISTOPHER L. CHIN
PRIMARY EXAMINER
GROUP ~~1800~~ 1641